COVID-19 Monoclonal Antibody Treatment
Educational Material and Consent Form

Patient name _____Date of Birth_____
Address: _____
Social Security # _____- _____- _____ Phone # _____
Facility name: Corner Drugs _____
Name of provider conducting informed consent_____

Facts about the COVID-19 Emergency Use Authorization (EUA)

Coronavirus is the virus that causes a disease called COVID-19. The virus is passed from person to person mostly by small droplets. These droplets come from the nose or mouth when an infected person coughs, sneezes, or speaks. Some people who are infected have no symptoms. Others have mild symptoms such as a cough and extreme tiredness. Other people have severe problems and may even die. COVID-19 has caused a worldwide pandemic.

The Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for monoclonal antibody treatment. With an EUA, drugs are not reviewed in the same way as an FDA-approved or cleared product. The FDA may grant an EUA when certain standards are met, for instance, when there are no other choices for treating a health problem like COVID-19. The FDA issues EUAs based on scientific proof that shows the product is likely to be safe and effective.

These monoclonal antibodies are being studied to treat COVID-19 in non-hospitalized patients with mild to moderate symptoms of COVID-19 who are at high risk for severe COVID-19 problems and/or a hospital stay. The drugs are being studied in patients who are not in the hospital. They must be 12 or older and weigh at least 88 pounds, have a positive COVID test, treated within 10 days of symptom onset, not needing oxygen therapy due to COVID-19. Because the drug is still being studied, there is limited information on how safe or effective it is. After this drug treatment has been used on more people, additional side effects may be noted.

Risks and Common Problems

There are risks linked to monoclonal antibody treatment, which include but are not limited to:

Allergic reaction: All kinds of allergic reactions can happen; You could have a minor reaction, such as a rash, or a severe reaction, such as swelling of your lips, face, or throat; A severe allergic reaction is a medical emergency that can cause death.

Changes in your heartbeat, chest discomfort or chest pain

Chills, fever, shivering, muscle aches, or headache

Confusion

Itching or rash

Low blood pressure or dizziness

Nausea, vomiting or sweating

Shortness of breath or wheezing

Weakness or feeling tired

All drugs can cause side effects. Problems that are not expected may happen. These problems may be life threatening. If you have any severe symptoms after the treatment, seek medical attention immediately.

More Facts

Monoclonal antibody treatment is not appropriate for patients who are already in the hospital or need increased oxygen therapy due to COVID-19.

It is possible that this treatment could reduce your immune response to a COVID-19 vaccine. The Centers for Disease Control (CDC) recommends waiting 90 days before getting a COVID-19 vaccine.

You will get the drug, REGEN-COV through 4 separate sub-cutaneous injections (just under the skin). This process will take a few minutes. You will be given 4 injections of the same medication (Regen-Cov) and will be monitored for at least one hour after the treatment. You will be required to remain on-site for 1 hour, so you can be monitored

Tell your pharmacist if you:

- have needed oxygen due to COVID-19 or on home oxygen;
- are pregnant or plan to become pregnant;
- are breastfeeding (lactating) or plan to breastfeed;
- have any serious health conditions, or;
- are taking any drugs (prescription, over-the-counter, vitamins, and herbals).

After you get this treatment, you will still need to continue to self-isolate, wear a mask, social distance, not share personal items, clean any commonly shared areas, and wash your hands often.

Treatment of Pregnant or Lactating Women

There is limited experience treating pregnant women or breastfeeding mothers with monoclonal antibodies. It is recommended that pregnant women should only be given the drug if the potential benefit outweighs the risk for the patient and her baby.

Consent to Treatment

This consent form told you about COVID-19 monoclonal antibody treatment and its most common risks. If, after reviewing this form, you do not believe that you understand the risks and your choices, then **do not sign the form until all your questions have been answered.**

I have given my provider an updated medical history.

I understand the facts provided to me in this consent form, and it is my choice to receive COVID-19 monoclonal antibody treatment. I give my consent for this treatment. By signing below, I agree that the pharmacist has discussed the facts in this form with me, that no one has given me any guarantee about the treatment, that I have had a chance to ask questions, and that all of my questions have been answered. I understand that I will need to remain on site for 1 hour.

I agree I was given a copy of the monoclonal antibody treatment fact sheet today.

I have ___ no known drug allergies **or** ___ the drug allergies listed below:

_____

_____ _____
Signature of Patient or Responsible Party Date and Time

_____
Relationship to Patient (if Responsible Party is not Patient)

_____ _____
Witness Date and Time

_____ _____
Provider Date and Time